Remarks

A. Pending Claims

Claims 1- 6, 8 - 28, 53, 75, 97, 116, and 140 are pending in the application. Claims 1- 28, 53, 75, 97, and 116 have been rejected. Claim 7 has been cancelled. Claims 1, 8-9, 28, 97, and 116 have been amended. Claim 140 is new.

B. Non-Statutory Obviousness-Type Double Patenting Rejections

The Office Action includes a rejection of claims 1-28, 53, 75, 97, and 116 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of copending U.S. Patent Application No. 10/235,295. Applicant respectfully disagrees with these rejections.

Applicant respectfully disagrees with the Office Actions rejection of claims 1-28, 53, 75, 97, and 116; however, to expedite prosecution of the application, Applicant has submitted a terminal disclaimer as an accompanying document.

Applicant respectfully requests that the rejections of claims 1-28, 53, 75, 97, and 116 be removed.

C. Objections To Specification

The Office Action includes an objection to the specification.

The Office Action states:

> The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 32, line 31 and page 45, line 26 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant has amended the specification herewith..

D. The Claims Are Not Anticipated By Whayne Pursuant To 35 U.S.C. § 102(a)

Claims 1-8, 10, 12-23, and 25 were rejected pursuant to 35 U.S.C. §102 a) as being anticipated by U.S. Patent No. 6,887,192 to Wayne et al. (herein after "Whayne"). Applicant respectfully disagrees.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

The Office Action states:

> Whayne et al. disclose an apparatus for reinforcing the endocardial surface of ventricle, with reinforcing elements giving the apparatus a first and second predetermined shape. The first shape is configured to be inserted into a catheter, which is moved through the vasculature to the heart (col. 16, lines 2-8).

Applicant respectfully submits that the cited art does not appear to teach or suggest the combination of features in claims 1-8, 10, 12-23, and 25.

Claim 1 describes a combination of features including, but not limited to, the feature of: "an adjustment mechanism, wherein the adjustment mechanism is configured, upon activation by a surgeon, to change a dimension of at least a portion of the second predetermined shape of the reinforcing element upon positioning the reinforcement element in the ventricle."

Whayne discloses:

> Support structures located along the endocardial surface of the right and/or left ventricle may be combined with support structures located along the epicardial surface to enhance the transfer of energy from viable tissue to less viable or non-viable tissue, especially when several injured tissue regions are dispersed throughout the heart. The support structures may be independent such that the endocardial support structures are not attached to the epicardial support structures. Alternatively, individual support links of the endocardial support structures may be inserted through the myocardium and may be connected to epicardial support structures so as to interconnect the expansion and contraction of the endocardial support structures to the epicardial support structures. This is especially relevant when the injured tissue extends from the interventricular septum to the left ventricular free wall and the desired position of the support structure extends from the right ventricular endocardial surface of the interventricular septum through the myocardium of the right ventricle and along the epicardial surface of the left ventricle. Other combinations of endocardially and epicardially positioned support structures may be used to address other indications or injured tissue locations. (Whayne, column 11, line 61 through column 12, line 14).

Wayne appears to teach or suggest connecting individual endocardial and epicardial support structures such that energy may be transferred from one support structure to another. Wayne does not appear to teach or suggest the combination of features in the claims, including but not limited to "an adjustment mechanism, wherein the adjustment mechanism is configured, upon activation by a surgeon, to change a dimension of at least a portion of the second predetermined shape of the reinforcing element upon positioning the reinforcement element in the ventricle."

Applicant submits, that many of the claims dependent on claim 1 are separately patentable. Applicant requests removal of the anticipation rejection of claims 1-8, 10, 12-23, and 25.

E. <u>The Claim Is Not Anticipated By Whayne Pursuant To 35 U.S.C. § 102(a)</u>

Claim 28 was rejected pursuant to 35 U.S.C. §102 (a) as being anticipated by Whayne. Applicant respectfully disagrees.

The Office Action states:

> Whayne et al. disclose an apparatus comprising a reinforcing element that attaches to a portion of the endocardial surface, where the apparatus inhibits the expansion of the endocardial surface over a cardiac cycle of the heart (col. 4, lines 26-34).

Applicant respectfully submits that the cited art does not appear to teach or suggest the combination of features in claim 28.

Claim 28 describes a combination of features including, but not limited to, the feature of: "a plurality of conduits that form the first predetermined shape, the second predetermined shape, or the first predetermined shape and the second predetermined shape; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit and to engage the portion of the endocardial surface when activated."

Whayne discloses:

> FIG. 12A shows a support structure 20 that incorporates an anchor 52 designed to penetrate into tissue. Anchor pins 54 extend radially away from anchor 52 at acute angles to maintain the position of the anchor within the tissue surface, once positioned. Anchor pins 54 may extend from the anchor in curves as shown in FIG. 12B, along lines as shown in FIG. 12C, or in other orientations. As shown in FIG. 12D, support structure 20 is secure to the tissue surface after anchor 52 is inserted through the first heart surface (epicardium 60 or endocardium 58) and anchor pins 54 are constrained from axial movement by the myocardium 56.
>
> Alternatively, the anchor may be inserted past the first heart surface (epicardium 60 or endocardium 58), through the myocardium 56, and past the second heart surface (endocardium 58 or epicardium 60) such that the anchor pins are constrained by the second heart surface. As shown in FIG. 12D, a tissue interface 18 spaces the support structure from the tissue surface, as will be described in detail below; even so, tissue

> interface 18 must enable insertion of the anchor during positioning and securing of the support structure. (Whayne, column 12, lines 47-67).

Whayne appears to teach or suggest anchors (52) coupled directly to support structures 20, which are capable of securing the support structure to the tissue surface. Whayne does not appear to teach or suggest the combination of features in the claims, including but not limited to "a plurality of conduits that form the first predetermined shape, the second predetermined shape, or the first predetermined shape and the second predetermined shape; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit and to engage the portion of the endocardial surface when activated."

Applicant requests removal of the anticipation rejection of claim 28.

F. <u>The Claim Is Not Anticipated By Whayne Pursuant To 35 U.S.C. § 102(a)</u>

Claim 53 was rejected pursuant to 35 U.S.C. §102 (a) as being anticipated by Whayne. Applicant respectfully disagrees.

The Office Action states:

> Whayne et al. disclose a reinforcing element on the apparatus that includes a plurality of conduits (26, 86, and 88) that form a predetermined shape, and elongated members 52 that, when activated, engage the portion of the endocardial surface.

Applicant respectfully submits that the cited art does not appear to teach or suggest the combination of features in claim 53.

Claim 53 describes a combination of features including, but not limited to, the feature of: "a plurality of conduits that form the predetermined shape during use; and at least one elongated member positionable in one or more of the plurality of conduits,

wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit when activated to engage the portion of the endocardial surface."

Whayne discloses:

> FIG. 12A shows a support structure 20 that incorporates an anchor 52 designed to penetrate into tissue. Anchor pins 54 extend radially away from anchor 52 at acute angles to maintain the position of the anchor within the tissue surface, once positioned. Anchor pins 54 may extend from the anchor in curves as shown in FIG. 12B, along lines as shown in FIG. 12C, or in other orientations. As shown in FIG. 12D, support structure 20 is secure to the tissue surface after anchor 52 is inserted through the first heart surface (epicardium 60 or endocardium 58) and anchor pins 54 are constrained from axial movement by the myocardium 56.
>
> Alternatively, the anchor may be inserted past the first heart surface (epicardium 60 or endocardium 58), through the myocardium 56, and past the second heart surface (endocardium 58 or epicardium 60) such that the anchor pins are constrained by the second heart surface. As shown in FIG. 12D, a tissue interface 18 spaces the support structure from the tissue surface, as will be described in detail below; even so, tissue interface 18 must enable insertion of the anchor during positioning and securing of the support structure. (Whayne, column 12, lines 47-67).

Whayne appears to teach or suggest anchors (52) coupled directly to support structures 20, which are capable of securing the support structure to the tissue surface. Whayne does not appear to teach or suggest the combination of features in the claims, including but not limited to "a plurality of conduits that form the predetermined shape during use; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit when activated to engage the portion of the endocardial surface."

Applicant requests removal of the anticipation rejection of claim 53.

G. The Claims Are Not Anticipated By Buckberg Pursuant To 35 U.S.C. § 102(b)

Claim 97 was rejected pursuant to 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 6,024,096 to Buckberg (herein after "Buckberg"). Applicant respectfully disagrees.

The Office Action states:

> Buckberg discloses, in the claims, a method for reinforcing a portion of the endocardial surface of the heart providing a patch, positioning and releasably attaching the patch to the ventricular wall. See col. 12, lines 41-46, and col. 9, line 67.

Applicant respectfully submits that the cited art does not appear to teach or suggest the combination of features in claim 97.

Claim 97 describes a combination of features including, but not limited to, the feature of: "accessing an interior of a left or right ventricle of the human heart subsequent to a cardiovascular event prior to substantial ventricular deformation."

Buckberg discloses:

> The procedure of the present invention addresses the effects of myocardial infarction using a cardioprotective approach to restore the geometry of the left ventricle. This is not a "remodeling" procedure automatically produced by the body 10, nor a "reconstructive" procedure which leaves the heart with other than a normal geometry. Rather, this is a procedure which attempts to "restore" the normal geometry, and particularly the apical configuration of the left ventricle 25. The procedure reduces the volume of the left ventricle 25, but also increases the percentage of the ventricle wall which is viable. This greatly increases the ejection fraction of the heart and significantly reduces heart stress.
>
> With a primary purpose of reducing the left ventricle volume, the intent of the procedure initially is to remove that portion of the wall which is not capable of contracting. This, of course, includes the scarred

> dyskinetic segments, which are easy to visualize, but may also include akinetic segments, which do not contract despite their normal appearances. (Buckberg, column 7, lines 29-47).

Buckberg appears to teach or suggest reducing the volume of an already naturally remodeled (e.g., enlarged) heart by removing nonviable tissue and positioning a shaped patch. Buckberg does not appear to teach or suggest the combination of features in the claims, including but not limited to "accessing an interior of a left or right ventricle of the human heart subsequent to a cardiovascular event prior to substantial ventricular deformation."

Applicant requests removal of the anticipation rejection of claim 97.

H. The Claims Are Not Anticipated By Buckberg Pursuant To 35 U.S.C. § 102(b)

Claim 116 was rejected pursuant to 35 U.S.C. §102 (b) as being anticipated by Buckberg. Applicant respectfully disagrees.

The Office Action states:

> Buckberg discloses a method of reinforcing a portion of a ventricle of a human heart, where the reinforcing element is attached so the natural contour of the region is maintained (col. 10, lines 59-63).

Applicant respectfully submits that the cited art does not appear to teach or suggest the combination of features in claim 116.

Claim 116 describes a combination of features including, but not limited to, the feature of: "attaching a reinforcing element to a region of an endocardial surface of the ventricle subsequent to a cardiovascular event prior to substantial ventricular deformation, wherein the reinforcing element is attached such that at least a portion of a natural contour of the region is maintained."

Buckberg discloses:

> The procedure of the present invention addresses the effects of myocardial infarction using a cardioprotective approach to restore the geometry of the left ventricle. This is not a "remodeling" procedure automatically produced by the body 10, nor a "reconstructive" procedure which leaves the heart with other than a normal geometry. Rather, this is a procedure which attempts to "restore" the normal geometry, and particularly the apical configuration of the left ventricle 25. The procedure reduces the volume of the left ventricle 25, but also increases the percentage of the ventricle wall which is viable. This greatly increases the ejection fraction of the heart and significantly reduces heart stress.
>
> With a primary purpose of reducing the left ventricle volume, the intent of the procedure initially is to remove that portion of the wall which is not capable of contracting. This, of course, includes the scarred dyskinetic segments, which are easy to visualize, but may also include akinetic segments, which do not contract despite their normal appearances. (Buckberg, column 7, lines 29-47).

Buckberg appears to teach or suggest reducing the volume of an already naturally remodeled (e.g., enlarged) heart by removing nonviable tissue and positioning a shaped patch. Buckberg does not appear to teach or suggest the combination of features in the claims, including but not limited to "attaching a reinforcing element to a region of an endocardial surface of the ventricle subsequent to a cardiovascular event prior to substantial ventricular deformation, wherein the reinforcing element is attached such that at least a portion of a natural contour of the region is maintained."

Applicant requests removal of the anticipation rejection of claim 116.

I. The Claim Is Not Obvious Over Whayne In View of Rubin Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claim 9 under 35 U.S.C. 103(a) as obvious over Whayne in view of U.S. Patent No. 5,910,124 to Rubin (herein after "Rubin"). Applicant respectfully disagrees with the rejection.

In order to reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177-178 (C.C.P.A. 1967). To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP § 2143.03.

The Office Action states:

> Whayne et al disclose a mechanism for engaging the device with the surface of the ventricle. However, Whayne et al. fails to disclose an adjustment mechanism for this device. Rubin teaches a source of gas pressure applied through the tube to change the dimensions of the reinforcing element. While gas pressure may not be practical for the design of the apparatus of Whayne et al., other mechanisms or modifications to Whayne's device, such as release mechanisms or fluid activation mechanisms exist to actuate the change between a first shape and a second shape.

Applicant respectfully disagrees. Claim 9 describes a combination of features including, but not limited to, the feature of: "an engagement mechanism configured to inhibit the activated adjustment mechanism from moving." Applicant submits that at least the above quoted features of claim 9, in combination with the other features of the claims, do not appear to be taught or suggested by the cited art.

An obvious rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in the reference, is not proper and the case of obviousness cannot be properly made. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As the Office Action states the Whayne and Rubin may not be easily, if at all, combined. In addition, neither reference appears to teach or suggest the combination of features in the claims, including but not limited to "an engagement mechanism configured to inhibit the activated adjustment mechanism from moving."

Applicant requests removal of the obviousness rejection of claim 9.

J. The Claim Is Not Obvious Over Whayne In View of Buckberg Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claim 11 under 35 U.S.C. 103(a) as obvious over Whayne in view of Rubin. Applicant respectfully disagrees with the rejection.

The Office Action states:

> Whayne et al disclose a ventricular reinforcement apparatus that acts to stabilize the endocardial surface during contraction and expansion of the ventricle. Whayne et al. fail to disclose a patch in the apparatus. Buckberg teaches a patch 72 that is secured to the endocardial surface and avoids distortion during contraction and expansion, while reducing the dead space in the ventricle.

Applicant respectfully disagrees. Claim 11 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element comprises a patch." Applicant submits that at least the above quoted features of claim 11, in combination with the other features of the claims, do not appear to be taught or suggested by the cited art.

Whayne discloses:

> The approach described by this invention, which uses a heart support structure to transfer energy (in the form of artificial contraction and expansion) from viable heart tissue to less viable or non-viable heart tissue, addresses the deficiencies of prior approaches, which purely reduce the end-diastolic diameter of the heart. This invention aids the heart during systolic ejection and diastolic filling to better restore normal functionality of the heart. The heart support structure controls the motion of the heart and synchronizes the contraction and expansion of diseased tissue to that of viable tissue.
>
> The heart support structure also accounts for the natural motion of the heart. As the heart contracts, the cross-sectional diameters of the ventricles decrease and the distance from the mitral valve annulus to the apex of the heart also decreases; as the heart expands, the cross-sectional-

diameters of the ventricles increase and the distance from the mitral valve annulus to the apex of the heart also increases. The optimal ratios of expansion (and contraction) between the cross-sectional diameters of the ventricles and the distance from the mitral valve annulus to the apex of the heart may be incorporated in the support structure to further preserve heart functionality. The heart support structure therefore preserves the wall motion and prevents remodeling of the diseased tissue by inhibiting over-expansion and maintaining normal actuation of all phases of the cardiac cycle. As a result, the dyssynchrony, hypokinesis, dyskinesis or akinesis, which occurs when tissue remodels over time, is inhibited. (Whayne, column 4, lines 7-35).

Buckberg discloses:

The procedure of the present invention addresses the effects of myocardial infarction using a cardioprotective approach to restore the geometry of the left ventricle. This is not a "remodeling" procedure automatically produced by the body 10, nor a "reconstructive" procedure which leaves the heart with other than a normal geometry. Rather, this is a procedure which attempts to "restore" the normal geometry, and particularly the apical configuration of the left ventricle 25. The procedure reduces the volume of the left ventricle 25, but also increases the percentage of the ventricle wall which is viable. This greatly increases the ejection fraction of the heart and significantly reduces heart stress.

With a primary purpose of reducing the left ventricle volume, the intent of the procedure initially is to remove that portion of the wall which is not capable of contracting. This, of course, includes the scarred dyskinetic segments, which are easy to visualize, but may also include akinetic segments, which do not contract despite their normal appearances. (Buckberg, column 7, lines 29-47).

Whayne appears to teach or suggest a heart support structure to transfer energy from viable heart tissue to less viable or non-viable heart tissue preserving the wall motion and prevents remodeling of the diseased tissue by inhibiting over-expansion and maintaining normal actuation of all phases of the cardiac cycle. Buckberg appears to teach or suggest reducing the volume of the left ventricle by surgically excluding nonviable tissue and using a shaped patch in an attempt to restore the original geometry of the heart. As the Office Action points out the patch of Buckberg is designed to avoid distortion during contraction and expansion, therefore it would appear that Buckberg's patch would be incapable of transferring energy and maintaining normal actuation of all

phases of the cardiac cycle as Whayne appears to teach. Applicant respectfully submits the modifying Whayne with Buckberg would destroys the intent, purpose or function of the invention disclosed in Whayne, and the rejection is therefore not proper and the case of obviousness cannot be properly made.

Applicant requests removal of the obviousness rejection of claim 11.

K. The Claims Are Not Obvious Over Whayne In View of Rubin Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claims 24, 26, and 27 under 35 U.S.C. 103(a) as obvious over Whayne in view of Rubin. Applicant respectfully disagrees with these rejections.

The Office Action states:

> Whayne et al disclose a ventricular reinforcement apparatus that acts to stabilize the endocardial surface during contraction and expansion of the ventricle. ... However, Whayne et al. lack a guidewire used to insert the device into the ventricle. Rubin teaches an inserter wire adapted to attach to the ventricular device, inserted into a tube, and used to accurately position the ventricular device within the endocardial surface.

Applicant respectfully disagrees. Claim 24 describes a combination of features including, but not limited to, the feature of: "wherein the center region comprises an opening configured to allow at least a guidewire to pass through the center region, and wherein the guidewire is configured to facilitate positioning of the reinforcing element on the endocardial surface." Claim 26 describes a combination of features including, but not limited to, the feature of: "a flexible conduit comprising a distal end configured to be inserted in a vasculature of a human body and positioned in a ventricle of the human heart." Claim 27 describes a combination of features including, but not limited to, the feature of: "a guidewire positionable in a flexible conduit, wherein the guidewire is configured to extend beyond a distal end of the flexible conduit during use, and wherein the guidewire is configured to releasably attach to an endocardial surface of the heart."

Applicant submits that at least the above quoted features of claims 24, 26, and 27, in combination with the other features of the claims, do not appear to be taught or suggested by the cited art.

Whayne discloses:

> The approach described by this invention, which uses a heart support structure to transfer energy (in the form of artificial contraction and expansion) from viable heart tissue to less viable or non-viable heart tissue, addresses the deficiencies of prior approaches, which purely reduce the end-diastolic diameter of the heart. This invention aids the heart during systolic ejection and diastolic filling to better restore normal functionality of the heart. The heart support structure controls the motion of the heart and synchronizes the contraction and expansion of diseased tissue to that of viable tissue.
>
> The heart support structure also accounts for the natural motion of the heart. As the heart contracts, the cross-sectional diameters of the ventricles decrease and the distance from the mitral valve annulus to the apex of the heart also decreases; as the heart expands, the cross-sectional-diameters of the ventricles increase and the distance from the mitral valve annulus to the apex of the heart also increases. The optimal ratios of expansion (and contraction) between the cross-sectional diameters of the ventricles and the distance from the mitral valve annulus to the apex of the heart may be incorporated in the support structure to further preserve heart functionality. The heart support structure therefore preserves the wall motion and prevents remodeling of the diseased tissue by inhibiting over-expansion and maintaining normal actuation of all phases of the cardiac cycle. As a result, the dyssynchrony, hypokinesis, dyskinesis or akinesis, which occurs when tissue remodels over time, is inhibited. (Whayne, column 4, lines 7-35).

Rubin discloses:

> Cardiac ventricular assist apparatus adapted to be placed by insertion through an incision in the wall of the upper abdomen below the rib cage and an incision in the inferior aspect of the pericardium proximate the heart apex comprises a flexible bladder assembly that adapted to be passed through the incision in the pericardium to a position between the pericardial sac and the epicardium. The bladder assembly is of a size such and shape such as to be engageable with a substantial portion of the outer surface of the left ventricle of a heart. The bladder assembly includes a

> distensible pumping bladder that is attached to a tube through which a gas can be introduced into it to compress the left ventricle and withdrawn from it to allow the ventricle to fill and a non-distensible retaining bladder, which is substantially coextensive with the pumping bladder and receives a packed body of particulate material. (Rubin, abstract).

Whayne appears to teach or suggest a heart support structure to transfer energy from viable heart tissue to less viable or non-viable heart tissue preserving the wall motion and prevents remodeling of the diseased tissue by inhibiting over-expansion and maintaining normal actuation of all phases of the cardiac cycle. Rubin appears to teach or suggest introducing a ventricular assist apparatus through an incision in the upper abdomen and positioned between the pericardial sac and the epicardium (not in the endocardial surface as the Office Action states). The cited art either separately or in combination do not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the center region comprises an opening configured to allow at least a guidewire to pass through the center region, and wherein the guidewire is configured to facilitate positioning of the reinforcing element on the endocardial surface." The cited art either separately or in combination do not appear to teach or suggest the combination of features in the claims, including but not limited to "a flexible conduit comprising a distal end configured to be inserted in a vasculature of a human body and positioned in a ventricle of the human heart." The cited art either separately or in combination do not appear to teach or suggest the combination of features in the claims, including but not limited to "a guidewire positionable in a flexible conduit, wherein the guidewire is configured to extend beyond a distal end of the flexible conduit during use, and wherein the guidewire is configured to releasably attach to an endocardial surface of the heart."

Applicant requests removal of the obviousness rejection of claims 24, 26, and 27.

L. The Claim Is Not Obvious Over Whayne In View of Rubin Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claim 75 under 35 U.S.C. 103(a) as obvious over Whayne in view of Rubin. Applicant respectfully disagrees with the rejection.

The Office Action states:

> Whayne et al disclose a ventricular reinforcement apparatus that acts to stabilize the endocardial surface during contraction and expansion of the ventricle. ... However, Whayne et al. lack a guidewire used to insert the device into the ventricle. Rubin teaches an inserter wire adapted to attach to the ventricular device, inserted into a tube, and used to accurately position the ventricular device within the endocardial surface.

Applicant respectfully disagrees. Claim 75 describes a combination of features including, but not limited to, the feature of: "a guidewire positionable in the flexible conduit, wherein the guidewire is configured to extend beyond the distal end of the flexible conduit during use, and wherein the guidewire is configured to releasably attach to an endocardial surface of the heart." Applicant submits that at least the above quoted features of claim 75, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Whayne discloses:

> The approach described by this invention, which uses a heart support structure to transfer energy (in the form of artificial contraction and expansion) from viable heart tissue to less viable or non-viable heart tissue, addresses the deficiencies of prior approaches, which purely reduce the end-diastolic diameter of the heart. This invention aids the heart during systolic ejection and diastolic filling to better restore normal functionality of the heart. The heart support structure controls the motion of the heart and synchronizes the contraction and expansion of diseased tissue to that of viable tissue.
>
> The heart support structure also accounts for the natural motion of the heart. As the heart contracts, the cross-sectional diameters of the ventricles decrease and the distance from the mitral valve annulus to the apex of the heart also decreases; as the heart expands, the cross-sectional-diameters of the ventricles increase and the distance from the mitral valve annulus to the apex of the heart also increases. The optimal ratios of expansion (and contraction) between the cross-sectional diameters of the

> ventricles and the distance from the mitral valve annulus to the apex of the heart may be incorporated in the support structure to further preserve heart functionality. The heart support structure therefore preserves the wall motion and prevents remodeling of the diseased tissue by inhibiting over-expansion and maintaining normal actuation of all phases of the cardiac cycle. As a result, the dyssynchrony, hypokinesis, dyskinesis or akinesis, which occurs when tissue remodels over time, is inhibited. (Whayne, column 4, lines 7-35).

Rubin discloses:

> Cardiac ventricular assist apparatus adapted to be placed by insertion through an incision in the wall of the upper abdomen below the rib cage and an incision in the inferior aspect of the pericardium proximate the heart apex comprises a flexible bladder assembly that adapted to be passed through the incision in the pericardium to a position between the pericardial sac and the epicardium. The bladder assembly is of a size such and shape such as to be engageable with a substantial portion of the outer surface of the left ventricle of a heart. The bladder assembly includes a distensible pumping bladder that is attached to a tube through which a gas can be introduced into it to compress the left ventricle and withdrawn from it to allow the ventricle to fill and a non-distensible retaining bladder, which is substantially coextensive with the pumping bladder and receives a packed body of particulate material. (Rubin, abstract).

Whayne appears to teach or suggest a heart support structure to transfer energy from viable heart tissue to less viable or non-viable heart tissue preserving the wall motion and prevents remodeling of the diseased tissue by inhibiting over-expansion and maintaining normal actuation of all phases of the cardiac cycle. Rubin appears to teach or suggest introducing a ventricular assist apparatus through an incision in the upper abdomen (not through a human vasculature as the Office Action states) and positioned between the pericardial sac and the epicardium (not in the endocardial surface as the Office Action states). Rubin appears to teach or suggest an inserter wire attached to the distal edge of a bladder. The cited art either separately or in combination do not appear to teach or suggest the combination of features in the claims, including but not limited to "a guidewire positionable in the flexible conduit, wherein the guidewire is configured to extend beyond the distal end of the flexible conduit during use, and wherein the guidewire is configured to releasably attach to an endocardial surface of the heart."

Applicant requests removal of the obviousness rejection of claims 24, 26, and 27.

M. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

Applicant respectfully requests a three month extension of time. A fee authorization form has been submitted to cover fees associated with submission of an Information Disclosure Statement, request for a three month extension of time fees, and a Terminal Disclaimer. If any further extension of time is required, Applicant hereby requests the appropriate extension of time. If any further fees are required, or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-01801/EBM.

Respectfully submitted,

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